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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,741	10/10/2001	Om Reddy Gaddam	DRF. 3.0-021	8734

45776 7590 01/13/2006

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EXAMINER

RAO, DEEPAK R

ART UNIT PAPER NUMBER

1624

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/975,741	GADDAM ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-10, 78 and 83-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This office action is in response to the amendment filed on October 13, 2005.'

Claims 3, 5-6, 8-10, 12-22, 25, 35-37, 40-42, 45-47, 50-52, 55, 60-62, 65, 70 and 78-86 are pending in this application.

#### ***Election/Restrictions***

The elected invention of Group I, claims 78, 8-10 and 83-86 are under consideration. Claims 3, 5-6, 12-22, 25, 35-37, 40-42, 45-47, 50-52, 55, 60-62, 65, 70 and 79-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

#### ***Withdrawn Rejections/Objections:***

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

#### ***The following rejections are maintained:***

Claims 78, 8-10 and 82-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray et al., WO 99/20614 in view of Claussner et al., U.S. Patent No. 5,646,172. The reasons provided in the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'the references do not suggest modifying the free acid of

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Example 29 or the sodium salt of Example 30 in the direction of the present claims 78 and 83-86'. This is not found to be persuasive because the primary reference, Lohray (WO'614) teaches the compounds of formula (I) and the corresponding pharmaceutically acceptable salts thereof, including salts of the carboxylic acid moiety formed by organic bases such as lysine, guanidine, etc. The secondary reference Claussner in the analogous art of pharmaceutical compounds teaches the equivalency of various organic bases that are used in forming pharmaceutically acceptable salts of a given carboxylic acid. The secondary reference is introduced merely to show that one skilled in the art would have been motivated to select any of the organic bases including those of the instant claims, to form the pharmaceutically acceptable salt of the instant claims.

Next, applicant cites MPEP § 2143.01 and argues that 'the prior art must suggest the desirability of the claimed invention'. However, the primary reference, Lohray, clearly teaches the free form of the instantly claimed compounds and further, suggests various salt forms of the disclosed compounds. Thus, the primary reference provides sufficient motivation to one of ordinary skill in the art to prepare any of the salt forms of the disclosed compound, including those of instant claims. The secondary reference lists various forms of the salts those prepared from organic bases, which include the salt forms of the instant claims. Therefore, the prior art as a whole suggests salts of organic bases and thus provides motivation to combine the teachings of the references and prepare the instantly claimed compounds with the reasonable expectation of obtaining compounds having the same therapeutic activity as disclosed for the free acid form of the compound. Contrary to applicant's arguments, the primary reference teaches the free acid form of the claimed compound (Example 29) and clearly suggests to one of ordinary skill that

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other types of pharmaceutically acceptable salts of the free acids may be prepared which include alkali metal salts (like Na, etc.) and salts of organic bases (such as lysine, arginine, guanidine, etc.). The secondary reference teaches an expanded list of organic bases and thus, it is established that one of ordinary skill in the art would have been motivated to use any of the listed organic bases to form the salts.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Deepak Rao**  
**Primary Examiner**  
**Art Unit 1624**

January 7, 2006

Continuation of Disposition of Claims: Claims pending in the application are 3,5,6,8-10,12-22,25,35-37,40-42,45-47,50-52,55,60-62,65,70 and 78-86.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3,5,6,12-22,25,35-37,40-42,45-47,50-52,55,60-62,65,70 and 79-82.